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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,099	07/14/2000	Susumu Seino	P19771	5279

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Greenblum & Bernstein P L C
1941 Roland Clarke Place
Reston, VA 20191

EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/617,099	Applicant(s) SEINO ET AL.	
	Examiner Rita Mitra	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Applicants' election with traverse of Group II (claims 3-12) in paper #8 (filed on November 1, 2001) is acknowledged. The traversal is on the ground that Group I (protein), Group II (DNA) and Group IV (Diagnostic agent) are similar in their concepts, thus, a search for the DNA of Groups II and IV should cover areas relevant to the protein of Group I. In addition Applicants urge that a search for the antibodies of Groups III and V should cover areas relevant to the protein of Group I, therefore the searches for the groups should significantly overlap and the search burden would not be serious. The traversal has been fully considered and not found persuasive because Groups I, II, IV and Groups I, III, V are directed to different subject matter as shown by different classification across the groups. Additionally, the issue of the subject matter of each Group are different. Therefore, examination of all groups would present a search burden, because the searches of both the patent and non-patent technical literature are not co-extensive. For example, a search for the DNA does not result in a search of all literature for the protein nor the antibody (ies). In addition, a protein and a DNA cannot be substituted one for the other as each has different physical, chemical, and biological properties and functions. As to the commentary regarding filing fees, filing fees are not a criteria for non-restriction. Furthermore, applicants indicate that it was not stated in the office action that a definition of what is "materially different." Applicants' attention is drawn to the page 3 of the office action dated October 1, 2001 where a definition of "materially different process" has been indicated clearly.

The restriction requirement is still deemed proper and is therefore made **FINAL.**

Claims 1, 2 and 13-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 3-12 are currently pending and are under examination.

Priority

Applicant's claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged. This application claims a priority of a Japanese Application No. 11-288372, filed on October 8, 1999. Although, the instant application has provided a copy of this application, it fails to provide a certified copy of English translation in support of the priority date claimed. Therefore, the priority date granted is July 4, 2000, which is a filing date of this application.

Objections to Claims

Claims 10 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, it cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim 10 is multiply dependent from a previous multiply dependent claim 5. Claim 10 is/has been reviewed on the basis that it depends solely from the first listed claim in the multiple dependency. It is incumbent upon applicant to properly amend the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite a "gene" and "DNA" which reads on the natural, non-patentable, state of the DNA as for example in a mouse (claim 3+). The rejection would be overcome by the insertion of language indicating that the gene and DNA was isolated and/or purified, thus being removed from the natural environment.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 is drawn to a mouse gene that encodes the protein of SEQ ID NO: 1. Specification on pages 4-5 gives a description about a mouse gene that encodes a protein having an amino acid sequence set forth in SEQ ID NO: 1 and a mutant thereof, which has a property of interacting with a GDP/GTP exchange factor II. The specification does not provide a sequence of a gene, where gene means genomic DNA encoding a protein. It is art recognized that a gene

includes promoters and other regulatory elements as well as exons and introns. There are no indicated regulatory sequence(s) necessary for the expression of this gene nor there is any sequence of untranslated region that are described. SEQ ID NO: 2 is a cDNA sequence hence it contains only exons. There is no disclosure of the introns nor what the intron sequences are nor what the regulatory elements are and one skilled in the art would not have known the nucleic acid sequence. For these reasons, it requires undue experimentation to make the claimed invention, especially where in claim 5, any one or more nucleotides, singly or in any combination of insertion, deletion and substitution would have been included by the claim and for which the specification does not describe with particularity as to retention of function.

Claim 5, and the dependent claims 7 and 12 thereto, which are directed to a DNA having a nucleotide sequence with one or more nucleotides deleted, substituted, inserted or added relative to the nucleic acid sequence set forth in SEQ ID NO: 2 and a recombinant vector having the said modified DNA sequence. Specification while defining "one or more" indicates at page 5 that several (e.g. 3 or 4) to 10 nucleotides relative to SEQ ID NO: 2 would be modified, and at page 7 specification provides a general description on how a variety of mutants can be generated. However, the specification fails to provide any specific description of the structure and function of the mutants generated. While the specification in Example (page 14, lines 15-22, Fig. 4), and at page 9 describes and demonstrates that the full length DNA set forth in SEQ ID NO: 2 encoding the protein of SEQ ID NO: 1 has a property to interact with cAMP-GEFII, there is no disclosure about the biological activities of the claimed mutants. For the reasons set forth above, undue experimentation is necessary to make and use the claimed mutants encoding a protein that retains the property of interacting with cAMP-GEFII.

Claim 8 is directed to a fragment of a DNA sequence set forth in SEQ ID NO: 2. The specification fails to provide any description of the structure and function of the fragment claimed. While the specification in Example (page 14, lines 15-22, Fig. 4), and at page 9 describes and demonstrates that the full length DNA set forth in SEQ ID NO: 2 encoding the protein of SEQ ID NO: 1 has a property to interact with cAMP-GEFII, there is no disclosure about the biological activities of the claimed fragments. Without any guidance or suggestions a

skilled artisan would not be able to predict the structure of a fragment that would demonstrate the same activity as the activity of the full length DNA sequence of SEQ ID NO: 2. Thus, for the reasons set forth above, undue experimentation is required to make and use the claimed fragment encoding a protein that retains the property of interacting with cAMP-GEFII.

Claim 9 is directed to a probe comprising a DNA sequence that hybridizes to the DNA sequence set forth in SEQ ID NO; 2. Applicants have not sufficiently defined the specific conditions of stringency under which the hybridization is to take place. While describing Northern Blot and *In situ* hybridization at page 5 the specification indicates the sequence of the probe in lines 1-4 and 9-14, however, specification fails to provide the hybridization conditions. Therefore it requires undue experimentation to practice the invention.

Claim 10 is directed to a primer consisting of a partial sequence of the DNA sequence set forth in SEQ ID NO; 2. Specification fails to provide the specific sequence of the primer that would anneal to the DNA template of a sequence set forth in SEQ ID NO: 2. Therefore it requires undue experimentation to design and develop a suitable primer for practicing the invention.

Therefore, due to large quantity of experimentation necessary to determine an activity or property of the disclosed gene and the modified forms thereof, such that it can be determined how to use the claimed gene, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the specification fails to teach the skilled artisan how to make and use the claimed invention.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 3-7, 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 4 and 5 are rejected as being dependent upon non-elected claims. In addition it is suggested that claim 3 incorporate "SEQ ID NO: 1" into the claim.

Claims 4 and 5 are indefinite because of the term "under." The term "under" renders the claim indefinite. It is not clear whether or not the nucleotide sequence is encompassed by SEQ ID NO: 2. A replacement of term "under" with "of" would overcome this rejection. Claims 6, 7, 11 and 12 are included in the rejection because they are dependent upon a rejected claim and do not correct the deficiency of the claim from which they depend.

Claims 5 is indefinite because of the phrase "one or more." The phrase "one or more" renders the claim indefinite. It is not clear how many nucleotides are deleted, substituted, inserted, or added relative to the nucleotide sequence set forth in SEQ ID NO: 2, which has 4980 nucleotides. Furthermore, the position of these nucleotides in relation to the sequence of SEQ ID NO: 2 is also not clear. Claim 7 is included in the rejection because they are dependent upon a rejected claim and do not correct the deficiency of the claim from which they depend.

Claims 6 and 7 lack antecedent basis for "the coding region" in claim 4.

Claim 8 is indefinite as to what part is the part that the claim 8 refers to that is in claim 4.

Claim 10 is indefinite because of the term "partial sequence." The term "partial sequence" renders the claim indefinite. It is not clear how many nucleotides are there in this partial sequence that the said primer is consisting of. Also what is the position of the primer sequence relative to the sequence of claims 4-7?

Claim Rejections – 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-12 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wang et al. (J. of Biol. Chem. vol. 275 (26), pp 20033-20044, June 30, 2000). Wang et al. teach a cDNA with 5640 bp from a rat brain library, which encodes a large protein RIM2 with 1555 amino acid residues (see page 20035, col. 2, under "Identification and Molecular Cloning of RIM2," and Fig. 1, page 20036). RIM2 cDNA has 75.8% sequence identity to SEQ ID NO: 2 (see sequence alignment result, GenEmbl database, Accession NO: AF199322, July 4, 2000). This reads on claims 3, 5 and 7 (all as dependent from claim 2), which has any number of insertions, deletions and/or substitutions both singly and/or in any combination. See the sequence alignment attached to the Wang et al. reference. Claim 4 is also rejected because absent factual evidence to the contrary, the reference discloses a DNA that corresponds to DNA encoding the protein. Since claim 6 only requires a claim 4 DNA

corresponding to a protein of claim 1 (i.e. does not require 100% amino acid sequence identity) thus, absent factual data to the contrary it would have been obvious that the reference disclosed DNA encoding a protein corresponding to the protein of claim 1. As to claim 8, the Wang et al. reference discloses fragments that are/would have been those fragments that consist of part of the DNA of claim 4. The issue of the claim 9 probe is disclosed at page 20035, right column, under 'RNA Blotting Experiments' of the reference. As to primers, the claim 10 primer is to hybridize to the DNA of claim 4, which any DNA corresponding to the protein of claim 1. The Wang et al. reference discloses such DNA encoding a protein corresponding to the protein of claim 1, thus it is anticipated if not obvious that the strand complementary to the coding strand would have been a primer. The claims 11 and 12 vectors are set forth at page 20034 right column.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must

conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
December 12, 2001

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600